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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,969	01/20/2004	Anthony A. Nobles	STER.004DV1	4027

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/761,969	Applicant(s) NOBLES ET AL.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: typographical error in line 2 of par. [0002]. Method has been misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "the applicator" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claims 20 and 21 recite the limitation "the shaft portion". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuen (U.S. 4,984,564). Yuen discloses a method of examining a body cavity, the method comprising the steps of inserting an expandable body into the body cavity (col. 4 ll. 35-48), the expandable device having a proximal end and a distal end and an inner and outer surface extending between the proximal and distal ends, and a lumen defined by the inner surface extending between the proximal end and the distal end, wherein the longitudinal dimension between the proximal and distal ends is greater than the maximum transverse dimension of either of the proximal and distal ends (see fig. 3), and the outer surface between the proximal and distal ends has a maximum transverse dimension that is less than the maximum transverse dimension of either of the proximal and distal ends (see fig. 3), and expanding the device within the body cavity, wherein expansion of the expandable device causes the outer surface between the proximal and distal ends to exert a force against a wall of the body cavity (col. 2 ll. 16-20).

Regarding claim 2, Yuen discloses inflating the inflation chamber.

Regarding claims 3 and 4, there are supporting members (12, 14) at the proximal and distal ends of the device that are expandable (fig. 4, 5).

Regarding claim 13, see col. 4 ll. 27-29.

Regarding claim 14, Yuen discloses deactuating the device to a contracted configuration (col. 4 ll. 54-56).

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Oddo (U.S. 2,849,002). Oddo discloses a method of examining a body cavity, the method comprising the steps of inserting an expandable body into the body cavity (fig. 1), the expandable device having a proximal end and a distal end and an inner and outer surface extending between the proximal and distal ends, and a lumen (11) defined by the inner surface extending between the proximal end and the distal end, wherein the longitudinal dimension between the proximal and

distal ends is greater than the maximum transverse dimension of either of the proximal and distal ends (see fig. 5), and the outer surface between the proximal and distal ends has a maximum transverse dimension that is less than the maximum transverse dimension of either of the proximal and distal ends, and expanding the device within the body cavity, wherein expansion of the expandable device causes the outer surface between the proximal and distal ends to exert a force against a wall of the body cavity (col. 2 ll. 39-46). The membrane (34) portion shown in fig. 6 is inflated (col. 4 ll. 15-23).

Regarding claims 2-5, Oddo discloses inflating expandable supporting members with a fluid (col. 3 ll. 25-28). The supporting members are at the proximal and distal end of the expandable device.

Regarding claim 6, see col. 3 ll. 22-25.

Regarding claims 7 and 8, the membrane portion (34) between balloons (32 and 33) can be inflated (col. 4 ll. 15-23).

Regarding claim 9, Oddo discloses inflating a chamber provided within each of the supporting members through ducts 35 and 37.

Claims 18, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Solar (U.S. 5,403,341). Solar discloses a method of inserting an expandable device (10) into a body cavity, the expandable device having a proximal end being at least partially retained within a retaining portion of the applicator (see fig. 4a-4c), expanding the expandable device, and withdrawing the applicator through the expandable device (fig. 5a-5d).

Regarding claim 20, the retaining portion (distal (40) includes a curved portion formed at the distal end of the shaft portion (30) as seen in figs 4a and 4c where retaining portion first starts to cover the expandable device.

Regarding claim 22, the retaining portion has a retaining cavity and a tear line (42) (see fig. 4b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oddo (U.S. 2,849,002). Oddo discloses the method substantially as stated above and further discloses that the supporting members at the distal end and proximal end can be inflated separately (35, 37 in fig. 6; col. 4 ll. 5-8). Oddo discloses that the connecting region can be inflated by duct 40 but does not expressly disclose the proximal end of the device and the connecting region being in fluid communication and instead indicates that the connecting region has its own inflation port.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the proximal end of the device (33) and the connecting region (34) in fluid communication because Applicant has not disclosed that this provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Oddo's and applicant's method, to perform equally well with either a separate inflation port for the connecting region as taught by Oddo or the claimed proximal end in fluid communication with the connecting region because both configurations allow the proximal end and connecting region to be inflated in order to dilate a body cavity.

Therefore, it would have been prima facie obvious to modify Oddo to obtain the invention as specified in claims 10 and 11 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Oddo.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuen in view of Sinnreich (U.S. 3,882,852). Yuen discloses the method substantially as stated above including the use of the retractor for spreading apart the walls of natural body orifices (col. 1 ll. 14-15) in order to permit access for a desired surgical or medical treatment but does not expressly disclose inserting a medical instrument through the lumen or using the retractor in a cervix.

However, Sinnreich discloses that it is old and well known in the art to insert tools such as endoscopic instruments through expandable retractors (fig. 4) in order to perform medical treatment. Sinnreich discloses the use of such a retractor in cervix. Therefore, it would have been obvious to one of ordinary skill in the art to employ the device of Yuen in the cervix as made obvious by Sinnreich since the cervix is a natural body orifice that, when spread apart, allows a surgeon access to the uterus for intrauterine surgeries.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oddo in view of Ahmadi (U.S. 5,163,906). Oddo discloses the method substantially as stated above include deactuating the expandable device to a contracted configuration. Oddo fails to disclose deactuating the expandable device to a contracted configuration or contracting the proximal end of the device prior to contracting the distal end of the device.

However, deactuating an expandable device before removal from a body is well known in the art to one of ordinary skill. This minimizes trauma to the surrounding tissue during the removal. Ahmadi discloses that it is old and well known to first contract a proximal expandable member (2) prior to contracting a distal expandable member (1). This allows tissue that was

disturbed by the proximal member to be flushed and debris removed while the distal member continues to close off the more distal portion of a cavity or lumen. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Oddo to include the steps of deactuating the device to a contracted configuration before removal and deactuate the proximal end prior to the distal end as made obvious by Ahmadi in order to allow a user to flush any debris that is left in the vesical neck once bleeding has been controlled without the fluid entering the bladder.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuen in view of Norelli et al. (U.S. 5,342,385). Yuen discloses the method substantially as stated above including the use of the retractor for spreading apart the walls of natural body orifices (col. 1 ll. 14-15) in order to permit access for a desired surgical or medical treatment but does not expressly disclose using the retractor in a vagina.

However, Norelli et al. discloses that is old and well known in the art to use a fluid-expandable surgical retractor in a vagina (fig. 6). The fact that the retractor can be deflated allows for a thin profile, which aids in insertion of the device into the vagina. Therefore, it would have been obvious to one of ordinary skill in the art to method of Yuen to include the vagina as one of the natural body orifices into which the retractor may be inserted as made obvious by Norelli et al. in order to gain the advantage of being able to perform vaginal operations.

Claims 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallstén (U.S. 4,954,126). Wallstén discloses a method of inserting an expandable device into a body cavity, the expandable device (10) being at least partially retained within a retaining portion (46) of the applicator, and expanding the expandable device (col. 6 ll. 9-27, 33-40). Wallstén does not disclose removing the applicator through the lumen of the expandable device. However, it is old and well known in the art that the applicator of the prosthesis is removed after

the expandable prosthesis has been placed in its desired location and expanded. In order to remove the applicator disclosed by Wallstén, the retaining portion (46) must necessarily be pass through the lumen of the expandable device. Therefore, it would be obvious to modify the method of Wallstén to include the step of removing the applicator, which would pass through the lumen of the prosthesis necessarily during removal, so that the applicator does not remain in the body after it is no longer needed.

Regarding claim 20, the retaining portion is a curved portion formed at the distal end of a shaft portion (fig. 6).

Regarding claim 21, the retaining portion (46) is being considered a bell attached to a shaft portion.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solar in view of Anson (U.S. 6,706,064). Solar discloses the method substantially as stated above, but fails to disclose the use of an inflatable device for the expandable device.

However, Anson discloses that it is old and well known in the art to employ expandable devices that are inflated. In particular, Anson discloses that the expandable device may be inflated with a gel that hardens the device once it has been completely inflated (col. 4 ll. 52-62). Anson discloses that this inflatable device is advantageous over balloon expandable devices because balloon expandable devices commonly experience radial contraction once the balloon is removed (col. 1 ll. 23-30). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Solar to include the use of an inflatable expandable device as made obvious by Anson in order to avoid radial contraction of the device once the applicator has been removed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
9/7/2006


GLENN K. DAWSON
PRIMARY EXAMINER